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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|-----------------------------|
| 09/765,291 | 01/22/2001 | Joe W. Gray | 81906-719168 (175400US) | 9405 |
| 20350 7590 05/02/2012 KILPATRICK TOWNSEND & STOCKTON LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | EXAMINER BRUSCA, JOHN S | |
| | | | ART UNIT 1631 | PAPER NUMBER |
| | | | NOTIFICATION DATE 05/02/2012 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket@kilpatricktownsend.com
ipefiling@kilpatricktownsend.com
jlhice@kilpatrick.foundationip.com

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/765,291 | Applicant(s) GRAY ET AL. | |
| | Examiner JOHN S. BRUSCA | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2012.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 127, 128, 130, 131, 133, 134, 136-142, 146, 147 and 150-155 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 127, 128, 130, 131, 133, 134, 136-142, 146, 147, and 150-155 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Status of the Claims

1. Claims 127, 128, 130, 131, 133, 134, 136-142, 146, 147, and 150-155 are pending.

Claims 127, 128, 130, 131, 133, 134, 136-142, 146, 147, and 150-155 are rejected.

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Drawings

3. A response to the petition to accept color drawings received 02 March 2012 will be sent under separate cover.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 127, 128, 130, 131, 133, 134, 136-142, 146, 147, and 150-155 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. (U.S. Patent No. 6,280,929) as evidenced by Ribeiro et al (Blood Vol. 70, pages 948-953 (1987)).

The claimed subject matter is a cell stained with two nucleic acid probes. The two probes have a combined length of at least 50 kb. One of the probes hybridizes to an ABL gene telomeric to the 200 kb region between exons Ib and II, and the other probe hybridizes to a BCR gene. The cell comprises a chromosomal translocation that joins portions of the BCR gene and ABL gene. In some embodiments the ABL probe is at least 35 kb and the ABL probe is at least 18 kb, each probe is labeled with different fluorescent labels, the cell is in interphase and the probes appear as doublets, the translocation is a t(9;22)(q34;q11) translocation, the cells are from peripheral blood or human bone marrow, the cells are cultured, the translocation is diagnostic or prognostic for acute lymphocytic leukemia (ALL) or chronic myelogenous leukemia (CML), the translocation forms a Philadelphia chromosome, the BCR probe is PEM12, or the ABL probe is c-hu-ABL. In some embodiments the claimed subject matter is a kit comprising the c-hu-ABL probe or the PEM12 probe.

In columns 55-59 and figure 8 Gray et al. shows probes hybridized in situ to cells. The probes are shown in column 55, lines 19-31 to be the c-hu-ABL probe that is 35 kb and

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is specific to a site that is telomeric to the 200 kb region of ABL between exons Ib and II, and the PEM12 probe that is 18 kb and is specific to a site that is centromeric to a 5.8 kb breakpoint cluster region of the BCR gene. The stained cells are shown in figures 9A-9F, 10, and 12. The chromosomal translocation is shown to be a t(9;22)(q34;q11) translocation at column 57, lines 3-8, and in figures 9A and 9B as discussed in column 15, line 11. The probes are detected by using different fluorescent labels in column 55, lines 19-31. Doublet appearance in interphase cells is shown in column 57, lines 3-8 and figure 9A and 9B. Cells derived from peripheral blood or bone marrow are shown on column 55, line 67 through column 56 line 4. Culture of the cells before staining is shown in column 56, lines 1-4. Association of the translocation with ALL and CML are shown in column 7, lines 44-50 (which equates the translocation with the name Philadelphia chromosome), column 8, lines 60-63, column 10, lines 32-40, and column 24, lines 19-29. Kits comprising probes for tumor cytogenetics are shown in column 12, lines 45-51.

The cells of Gray et al. are shown to inherently be human cells that comprise a Philadelphia chromosome by Ribeiro et al. which shows on page 948 that a Philadelphia chromosome has a t(9;22)(q34;q11) translocation. Ribeiro et al. shows on page 948 that the Philadelphia chromosome is considered to be a marker of ALL and CLL in human patients.

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The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

6. The rejection of claims 127, 128, 130, 131, and 148 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 11 and 14 of U.S. Patent No. 6,280,929 in the Office action mailed 05 January 2012 is withdrawn in view of the disclaimer of claims 4 and 5 in U.S. Patent No. 6,280,929.

7. The rejection of claim 137 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 11, and 14 of U.S. Patent No. 6,280,929 in view of Bartram et al. in view of Ribeiro et al. in the Office action mailed 05 January 2012 is withdrawn in view of the disclaimer of claims 4 and 5 in U.S. Patent No. 6,280,929

Conclusion

8. A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN S. BRUSCA whose telephone number is (571)272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/

Primary Examiner, Art Unit 1631

jsb